

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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## Published

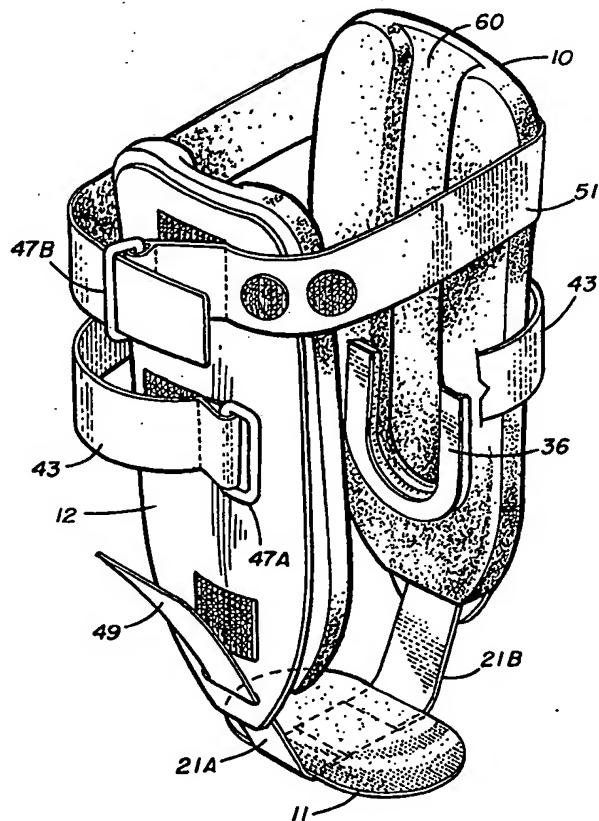
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

## (54) Title: THERAPEUTIC ANKLE ORTHOSIS

## (57) Abstract

This invention is a therapeutic ankle orthosis including an extended lateral shell (10) having an aperture (13) for receiving the fibular malleolus, and a lower end portion extending downwardly beneath that aperture (21A, 21B, 73). An extended medial shell (12) is adapted to fit beneath, and upwardly above the tibial malleolus. An optional foot plate (11) is adapted to underlie primarily the rear foot, and extend forwardly, optionally beyond the mid-tarsal joints. A U-pad (36) is secured to the inside of the lateral shell (10). A specific strapping method provides external compression.



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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****THERAPEUTIC ANKLE ORTHOSIS**

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**REFERENCE TO FIRST APPLICATION**

This application claims the benefit of U.S. Provisional Application No.60/089,080, filed June 12, 1998

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**Background of the Invention**

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At the outset a distinction is to be made between functional ankle braces and therapeutic ankle orthosis. An ankle brace is designed to limit the range of side-to-side foot motion during stressful functional activities. An ankle orthosis, on the other hand, serves as a functional ankle brace during the transitional period between resolution of acute sprain symptoms and complete restoration of normal ankle function and, at the same time, therapeutically treats and controls residual sprain symptoms.

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An example of an ankle brace of the prior art is that disclosed in U.S. Pat. No. 5,069,202. Its structure includes a foot shell pivoted to a leg shell which comprises lateral and medial uprights connected by an anterior band for holding the band against the leg of the wearer. Adjustable strap means are included for holding these components in operative position on the leg, ankle and foot. Another form of ankle brace is disclosed in U.S. Pat. No. 5,199,941 which includes medial and lateral shells connected to a foot shell, though without a pivotal joint between them. A therapeutic ankle orthosis is disclosed in U.S. Pat. No. 4,556,054 and includes a foot shell and a leg cuff interconnected by appropriate adjustable straps.

The prior art disclosure perhaps most pertinent to the present invention is German Gebrauschmuster (hereinafter referred to as the "Petty" patent) No. 68814157.8, published Feb. 9, 1989. It is intended to function therapeutically during recovery from acute sprain symptoms and at the same time to brace the ankle to limit the maximum range of

side-to-side foot motion. The therapeutic functions include compression and joint stabilization. The Petty patent teaches a foot shell pivotally and slidably connected to the lower end of lateral and medial shells by means of a post in a curved slot, with the components held together by adjustable strap means. The lateral shell includes an aperture for encircling the fibular malleolus and an inner pad for compression. The pad is not of U-shape, though pads of that configuration are known from such prior art patents as my U.S. Pat. No. 4,590,932 to disperse edema upwardly from those regions around the fibular malleolus where excess fluid accumulates.

5 The most common mechanism causing ankle ligament injury is inversion or turning inward of the sole of the foot. However, there is an associated mechanism which involves rotation of the foot and leg in opposite directions in a horizontal plane, referred to as adduction of the foot or internal foot rotation combined with external leg rotation. Prior art ankle braces emphasize means for restraining inversion of the foot but do little to protect against external rotation of the leg upon the foot that is relatively fixed with 10 respect to the ground.

15 In the [German] Petty patent referred to above, the articulation of the foot plate with respect to the lateral shell by means of a curved slot and rivet allows for a combination of rotational and gliding movement between the components. The curvature of the slot does not correspond to the functional axis of the upper ankle joint, namely the talocrural joint. Rotation of the foot and leg in opposite directions in a horizontal plane 20 would result in a spreading apart of the lateral and foot components of the Petty patent along the anterior margin of the overlapped areas. Such a design does not provide resistance to rotary ankle motion within the horizontal plane. Resistance to rotary motion can be provided by an oblique strap anchored on the lateral shell and the posteromedial 25 aspect of the leg.

#### Summary of the Invention

External compression for control of edema has traditionally been provided by elastic wraps. Wrapping the ankle with elastic material has the undesirable effect of

producing generalized pressure over the entire surface of the wrapped extremity. Resolution of ankle edema is greatly facilitated by a focal compression effect that compacts injured soft tissues, while leaving adjacent tissues uncompressed. This focal compression effect can be maximized by using specific strapping configurations and shell contouring. Strap tension over the brace shells results in the production of pressure against selected anatomical locations on the extremity. The interaction of the strapping configuration and shell configuration maximizes conformity of the U-pad to anatomical contours, thereby maximizing the edema drainage effect.

The present invention provides an advantage over the prior art devices and mechanism by discarding the rigid foot plate in favor of a soft foot plate component that allows the person wearing the brace, while the brace is on the ankle in position, to tighten the strap that runs up and under the bottom of the foot by pulling up on the medial side of the strap where it attaches, as with Velcro<sup>R</sup> couplings. By increasing the tension on the straps, it pulls the lower portion of the lateral pad in closer to the ankle. The effect of this is enhanced formability of the focal pressure pad to the anatomical contours around the malleolus, particularly the lower portion of what is referred to as the inferior aspect of the malleolus. So in addition to the anatomical conformity of the brace, it enhances the reduction of bulkiness to fit down into different styles of shoes. It is the added advantage of this ability to increase the tension of the strapping on the other surface of the device, where it is readily accessible to the wearer, so that it pulls the lateral shell and the underlying focal pressure pad in closer against the surface of the ankle and leg. Thereby added comfort is provided to the instep of the wearer with improved conformity to the ankle.

The therapeutic ankle orthosis of the invention includes an extended lateral shell having an aperture for receiving the fibular malleolus and having a lower end portion extending downwardly beneath that aperture. An extended medial shell is adapted to fit beneath and upwardly above the tibial malleolus. Optionally, a foot plate either rigid, semi-rigid or flexible is adapted to underlie primarily the rear foot and extend forwardly, optionally beyond the mid-tarsal joints. Pivoting means may connect the lower end

portion of the medial shell to the side portion of the foot plate permitting ankle movement of the foot plate relative to the medial shell about an axis substantially coincident with the functional axis of the talocrural joint. Securing means may be provided for holding together the medial shell and the lateral shell with the provided foot plate to resist ankle inversion and eversion while enhancing and providing comfortable fit and conformity of the focal compression pad. Adjustable strap means are included for holding the shells in operative position on the leg and ankle and foot.

The medial shell may be contoured generally to fit the lower leg and ankle. A U-pad is secured to the inside of the lateral shell and a pad 36 having a shape matching that of the lateral shell and having an aperture to receive the fibular malleolus may be secured to the inside of the lateral shell. Optionally, a pivot means for the strapping may be a rivet fixed to the medial shell outer surface and extending around the lower ankle to wrap around and beneath the foot, then through slots in the lateral shell side portion and having terminal portions connecting again to the medial shell and holding the opposing sides comfortably together.

The U-pad is preferably constructed with rounded edges along the margins of the edema drainage channel to enhance conformation of the U-pad to the normal anatomical contours of the lateral leg. Further, the U-pad may incorporate a silicone rubber inset or other soft material to enhance conformation of the U-pad to the normal anatomical contours of the fibular malleolus and to accentuate the application of external compression to the soft tissues on the periphery of the fibular malleolus in the anatomical areas referred to as the anterolateral and posterolateral gutters.

25        Optionally, a series of angled positioned slots may be formed in either the medial shell lower portion or the lateral shell lower portion. The angle of the slots may be centered about the axis of the normal pivot of the ankle. A second pair of angled slots complimentary to the first pair of angled slots may be formed in the medial or lateral shell lower end portion and spaced to cooperate with each other.

An optional securing means may extend through the slot intermediate the ends thereof when the leg and foot are vertical and horizontal, respectively. On the outer end

of the strapping there may be securing means for holding one shell against the other shell. The lateral and medial shell lower end portions are secured by the straps wrapped around and beneath the inside of the ankle and foot about the heel with the securing means affixed to the medial shell lower end portion.

5        The strapping means may include a first strap fixed at one end of a forward portion of the medial shell and threaded through slots in the lateral shell and adjustably secured at the opposite end to buckling means. A second strap may be provided which is fixed at one end to a rearward portion of the medial shell and threaded through slots in the lateral shell and adjustably securable as its opposite end to the buckling means.

10      Alternatively, a single continuous strap may be threaded through slots in the lateral shell, attached at one end to a forward portion of the medial shell and the other end attached to a rearward portion of the medial shell. Because the alternative strap configuration would not encircle the leg, an additional circumferential strap, with buckling means for adjustable strap tension, would be added to compress the medial and lateral shells against

15      the ankle and leg. There may be at least one circumferential leg strap affixed at one end to the upper portion of the medial side shell which would encircle both shells and be adjustably secured to itself by means of hook and pile fastener.

20      The lateral shell may be movable up and down and forward and rearward, with the strap or straps sliding in their respective lateral shell slots, to locate the lateral shell in a selected position relative to a user's fibular malleolus. The X-straps may be removably affixed to the underside of the foot plate or the lower end portion of the medial shell. The buckling or securing means for the first and second straps may overlie the medial shell by means of hook and pile fastener. The foot plate 11 is made of semi-rigid plastic or a pliable fabric, such as cotton, nylon with or without further padding, and the like.

25      The shells are preferably semi-rigid, by which is meant that they are stiff enough so that the lateral and medial shells, for example, do not significantly lose their leg or ankle-contoured shape under normal maximum adult weight, but are flexible enough to be depressed to exert extra localized pressure against the ankle behind a tightly fitted securing strap.

Brief Description of the Drawings

5 When a number is used in the following descriptions it is intended to include alternative views.

FIG. 1 is a perspective view of the therapeutic ankle orthosis of the invention viewed from the medial side.

FIG. 2 is a perspective of the lateral side of the assembled therapeutic ankle orthosis of FIG. 1.

10 FIG. 3 is a side view of the lateral side of the ankle orthosis of the invention using an alternative strap arrangement.

FIG. 4 is a side view of the medial side of the ankle orthosis of the invention of FIG 3.

15 FIG. 5 is a side view of yet another alternative strapping and fastening means of the lateral shell side of the ankle orthosis of the invention.

FIG. 6 is a side view of an alternative strapping and fastening means of the medial shell side of the ankle orthosis of the invention of FIG. 5.

Description of the Alternate Embodiments

20 Referring first to FIGS. 1 to 6, the therapeutic ankle orthosis of the invention includes at least two semi-rigid shells: namely, an extended lateral shell 10, a foot plate 11 and an extended medial shell 12. Each of the shells is of unitary molded plastic construction, perhaps of varying thickness to vary the degree of semi-rigidity in different portions of each shell. Polypropylene or polyethylene may be suitable materials for the shells. Each is contoured to fit generally against typical leg, ankle and foot anatomy 25 against which it is disposed during use.

The lateral shell 10 fits against and is contoured to the lateral side of the lower leg and ankle and may include an aperture 13 to receive the fibular malleolus. If desired, the lateral shell 10, foot plate 11, and medial shell 12 could each be symmetrical about its

longitudinal axis and therefore be reversible to fit on either the left or the right foot and ankle.

The lateral shell 10 shown in FIGS. 3 and 5 is adapted to fit beneath and upwardly about the fibular malleolus. It is of symmetrical configuration and can be used on either the left or the right ankle. It includes a slot 18 and a slot 19. Placed below these slots are slots 20A and 20B portions. The foot plate 11 is adapted to underlie the rear foot. It is in the form of a contoured stirrup which includes an upper medial side portion 21a and an optional lateral side portion 21b (FIGS 1 AND 2).

Shown in FIG. 1 is a U-pad 36 of self-supporting thermoplastic foam material or other appropriate material such as silicon or a capsule having U-shaped configuration filled with air, gel or the like. It is releasably secured to the inside of the lateral shell 10 by appropriate means such as quick-release hook-an-pile fastener patches sold under the trademark "Velcro<sup>R</sup>". The U-shaped configuration provides an upwardly open channel for translocation of edema from around the fibular malleolus. The "U-pad" is unitary with the shell or as an inset of material to provide to channel away swelling and produce compaction of soft tissue, especially around the fibular malleolus in the anatomical areas referred to as the anterolateral and posterolateral gutters.

Referring to FIGS. 3-6, the X-strap ends 40 and 41 are fixed to the forward and rearward portions respectively of the medial shell 12 by means of either hook and pile fastener or rivets. The forward attachment 40 secures one end of a strap 49 which is threaded through slots 20A and 18 in the lateral shell 10. Secured by the hook and pile fastener or rivet attachment 41 is a second strap 44 which is threaded through the slots 20B and 19. Straps 44 and 49 could be secured and adjustably tightened by passing them through a pair of D-rings 61 and 62 attached to the medial shell 12 (FIG 6), or alternatively, a pair of slots in the same relative proximity on the medial shell 12.

By tightening the straps 44 and 49 compression can be applied to the lateral shell 10 and thus to the U-pad 36 to compress the ankle directly forwardly and rearwardly of the fibular malleolus which is where edema tends to accumulate as a consequence of an ankle sprain. Alternatively, a single continuous strap may be threaded through slots 30A

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and 30B in the lateral shell, attached at one end to a forward portion of the medial shell and the other end attached to a rearward portion of the medial shell, FIGS. 3 and 4. Because the embodiment shown in FIGS. 1 and 2 does not incorporate the X-strap system, circumferential strap 43, with buckling means 47B for adjustable strap tension, would be added to compress the shells against the ankle and leg.

A leg strap 51 is affixed at one end by hook and pile fastener to the upper portion of the medial shell. The strap 51 may be adjustably tightened by being secured to itself by suitable hook-and-pile fastener or buckling means.

When the ankle orthosis of the invention is strapped to the foot as described above and as shown in FIGS. 1 to 6, several results are achieved. Most importantly, the U-pad 36 directs edema upwardly from around the fibular malleolus and compression is applied precisely where desired forwardly and rearwardly of the fibular malleolus. The lateral shell 10 and the U-pad 36 may be adjustable up and down and forwardly and rearwardly as shown in FIGS 3-6, with the X-strap system 44 and 49 sliding in its respective lateral shell slots 18, 19 and 20 to locate the lateral shell 10 properly relative to the user's fibular malleolus and direct edema upwardly from that area. Edema drainage is facilitated by channel 60 that molded into the lateral shell 10.

Hence, there is described hereinabove a system for the interactive effect of a U-shaped pad (attached to the inner surface of the lateral shell), lateral semi-rigid shell anatomical contour, said U-shaped pad adjustably positioned in the lateral shell location in relation to the position of the fibular malleolus (the bony prominence on the outer surface of the ankle) and a strapping system for accentuating the compression effect on the soft tissue surrounding the fibular malleolus for control of ankle swelling.

The foregoing specification describes the embodiments of the present invention shown and described. Other embodiments may be described as well. The terms and expressions used serve to describe the invention by example and are not limited to the invention. Differences may be noted, however, said differences do not depart from the scope, metes and bounds of the invention herein described and claimed. Known elements

having equivalent function may be used to replace of the specific constructional elements described.

The scope of this invention is to be determined by the following claims rather than the foregoing description of a preferred embodiment.

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I claim:

1. A therapeutic ankle orthosis comprising:

(a) a rigid lateral shell being contoured generally to fit the lower leg and ankle;

5 (b) a U-pad disposed beneath and upwardly about the fibular malleolus and releasably secured to the inside of the lateral shell;

(c) a rigid extended medial shell adapted to fit beneath and upwardly about the tibial malleolus;

10 (d) a pad covering and being releasably secured to the inside of the medial shell; and

(e) adjustable strap means for holding the shells in operative position on the leg and ankle and foot.

2. A therapeutic ankle orthosis according to Claim 1 wherein the strap means

15 comprises a strap fixed at one end to a forward portion of the medial shell and threaded through slots in the lateral shell secured at its opposite end to buckling means on the medial shell and turned back upon and adjustably secured to itself, a second strap fixed at one end to a rearward portion of the medial shell and threaded through slots in the lateral shell secured at its opposite end to buckling means on the medial shell, and one or more leg straps affixed at one end to the upper portion of either medial or lateral shell and adjustably secured at its opposite end to said upper portion or either the medial or lateral shell.

20 3. A therapeutic ankle orthosis comprising:

(a) a first semi-rigid lateral side shell and a second semi-rigid medial side shell adapted to fix in operative position against the ankle of a user;

25 (b) a U-pad releasably secured to the inside of said lateral shell to be disposed beneath and upwardly about the fibular malleolus;

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(c) adjustable strap means for holding the lateral side shell and pad in said operative position against the ankle comprising a strap adjustably secured at one end to a forward portion of the medial shell and threaded through slots in the lateral shell and adjustably secured at its opposite end to securing means on a rearward portion of the medial shell.

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4. A therapeutic ankle orthosis comprising:

(a) two extended side shells having a padding adapted to receive a malleolus and having a lower end portion extending downwardly beneath that aperture; and

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(b) adjustable strap means for holding the shells in operative position on the ankle and foot comprising a strap fixed at one end to a forward portion of the medial shell and threaded through slots in the side shell and a second strap fixed at one end to a rearward portion of the medial shell and threaded through slots in the side shell and adjustably secured at its opposite end to a said securing means.

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5. A therapeutic ankle orthosis comprising:

(a) an extended lateral shell having a vertical molded channel therein to facilitate edema drainage and having a lower end portion extending downwardly beneath the fibular malleolus;

(b) an extended medial shell adapted to fit beneath and upwardly about the tibial malleolus;

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(c) a foot plate adapted to underlie the rear foot and having an upper medial side portion extending upwardly to overlap the lower end portion of the medial shell and having an upper lateral side portion extending upwardly, which is connected to the lower end portion of the lateral shell;

(d) securing means for holding together the overlapping lower end portion of the medial shell and medial side portion of the foot plate;

(e) securing means for holding together the lower end portion of the lateral shell and the lateral side portion of the foot plate;

(f) adjustable strap means for holding the shells in operative position on the leg and ankle and foot and for applying focal compression to control edema of the  
5 ankle.

6. A therapeutic ankle orthosis according to Claim 5 including a means for connecting the lower end portion of the medial shell to the medial side portion of the foot plate permitting angular movement of the foot plate relative to the medial shell about an  
10 axis substantially coincident with the functional axis of the talocrural joint and a means for connecting the lower end portion of the lateral shell to the lateral side portion of the foot plate permitting optimal positioning of the lateral shell in relation to the fibular malleolus, regardless of whether it is applied to a right or left extremity, and permitting angular movement of the foot plate relative to the lateral shell about an axis substantially  
15 coincident with the functional axis of the talocrural joint.

7. A therapeutic ankle orthosis comprising:

(a) a contoured extended lateral shell having a vertical channel therein to facilitate edema drainage and having a lower end portion extending downwardly beneath the fibular malleolus and having a vertical molded channel therein;  
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(b) an extended medial shell adapted to fit beneath and upwardly about the tibial malleolus;

(c) a foot plate adapted to underlie the rear foot and having an upper medial side portion extending upwardly to overlap the lower end portion of the medial shell; and an upper lateral side portion extending upwardly, which is connected to the lower end portion of the lateral shell by means of hook and pile fasteners or rivets;  
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(d) securing means for holding together the lower end portion of the medial shell and the medial side portion of the foot plate;

(e) securing means for holding together the lower end portion of the lateral shell and the lateral side portion of the foot plate;

5 (f) adjustable strap means for holding the shells in operative position on the leg and ankle and foot for applying focal compression to control edema of the ankle, provided said securing means contains at least one adjustably securable strap through a D-ring and having a strapping arrangement to prevent the lateral shell from being displaced outwardly.

10 8. A therapeutic ankle orthosis according to Claim 1 wherein the U-pad is constructed with rounded edges along the margins of the edema drainage channel to enhance conformation of the U-pad to the normal anatomical contours of the lateral leg.

15 9. A therapeutic ankle orthosis according to Claim 1 wherein the U-pad incorporates a silicone rubber insert to enhance conformation of the U-pad to the normal anatomical contours of the fibular malleolus and to accentuate the application of external compression to the soft tissues on the periphery of the fibular malleolus.

10. A therapeutic ankle orthosis comprising:

20 (a) two semi-rigid side shells adapted to fit in operative position against the ankle of a user;

(b) said side shell having an aperture adapted to receive a malleolus of the user;

(c) a U-pad releasably secured to the inside of the lateral shell to be disposed beneath and upwardly about the fibula;

25 (d) a foot plate adapted to underlie the rear foot of the user and having strapping means interconnecting to a lower end portion of the medial side shell; and

(e) adjustable strap means for holding the side shell and pad in said operative position comprising a strap fixed at one end to a forward portion of the foot plate and threaded through slots in the side shell and adjustably secured at its opposite end

to securing means on the shell portions, and a strap fixed at one end to a rearward portion of the foot plate and threaded through slots in the lateral side shell and adjustably secured at its opposite end to said securing means.

5 11. A therapeutic ankle orthosis comprising:

(a) two extended side shells having an aperture adapted to receive a malleolus and having a lower end portion extending downwardly beneath that aperture;

(b) a foot plate adapted to underlie the rear foot;

10 (c) strap means connecting the lower end portion of the side medial shell to the side portion of the foot plate permitting angular movement of the foot plate relative to the side shell about an axis substantially coincident with the functional axis of the talocrural joint;

15 (d) securing means for holding together the overlapping lower end portion of the side shell and the strap means of the foot plate forwardly of the strap to resist ankle inversion and eversion; and

20 (e) further adjustable strap means for holding the shells in operative position on the ankle and foot comprising a strap fixed at one end to a forward portion of the foot plate and threaded through slots in the side shell and a strap fixed at one end to a rearward portion of the foot plate and threaded through slots in the side shell and adjustably secured at its opposite end to said securing means.

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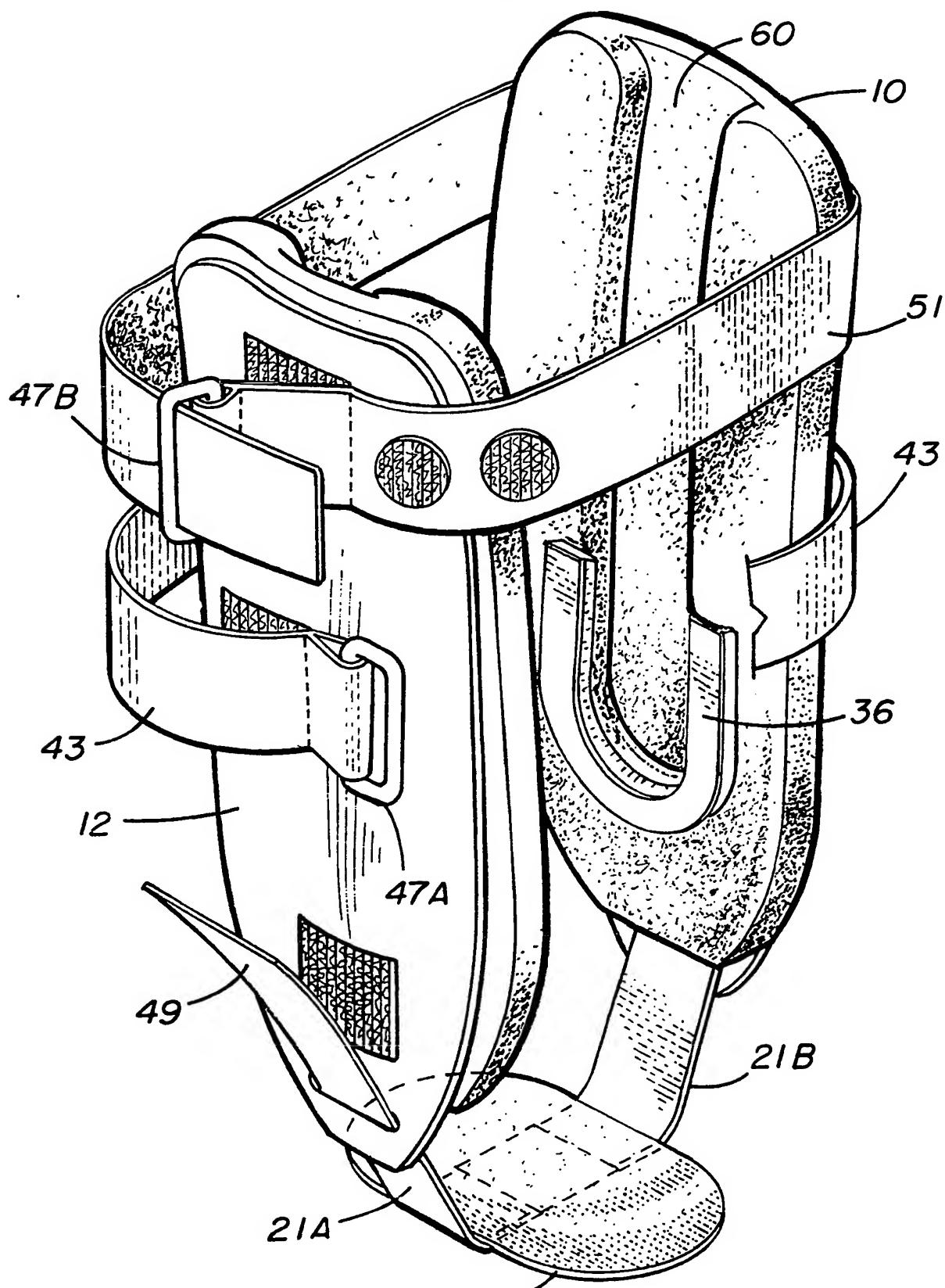
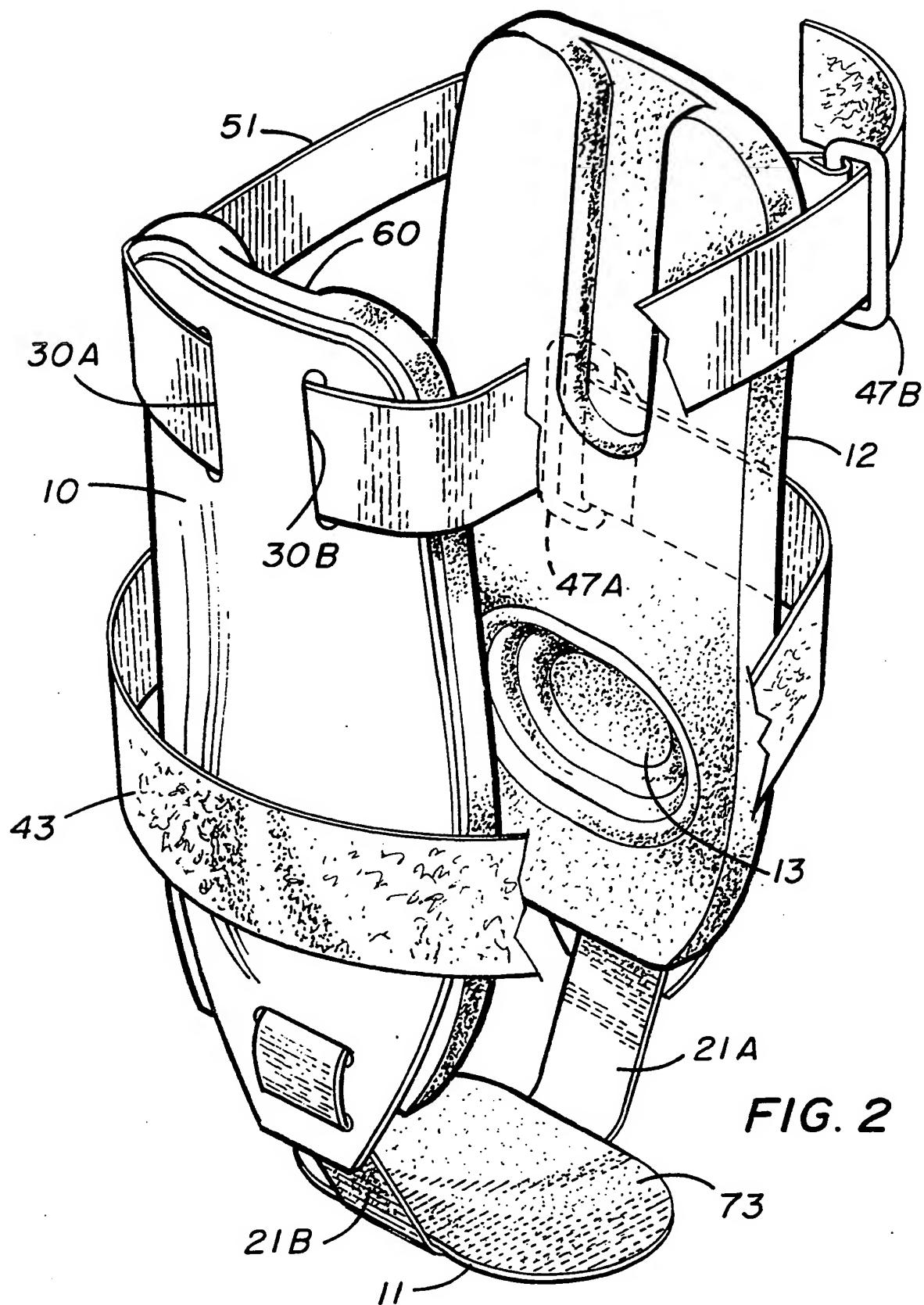


FIG. 1

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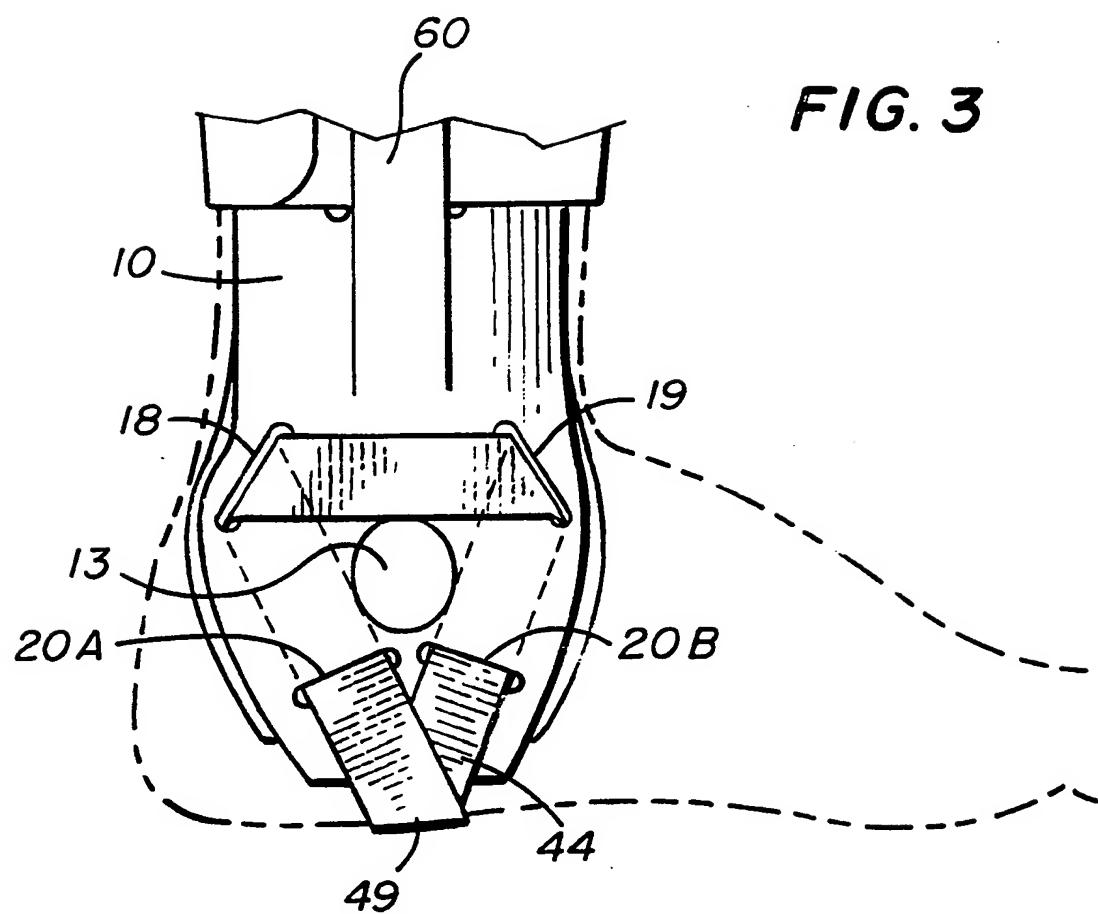
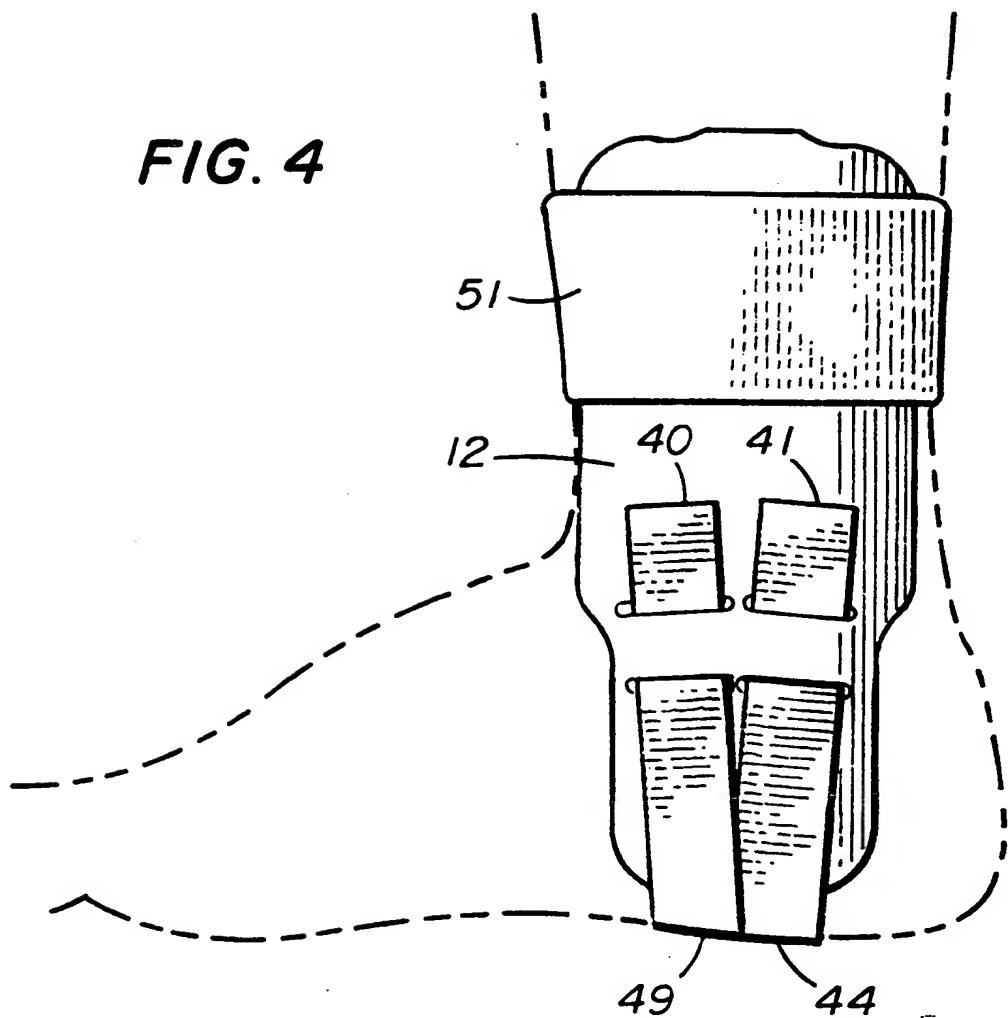
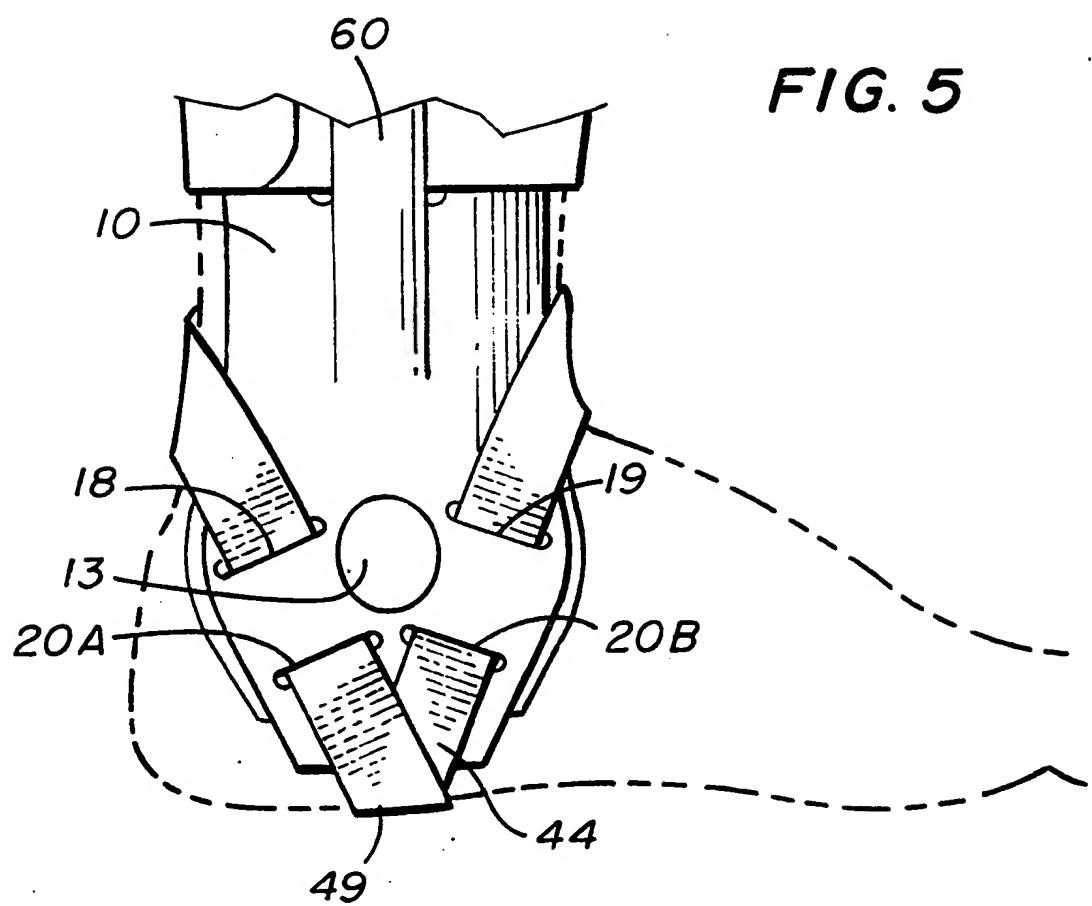


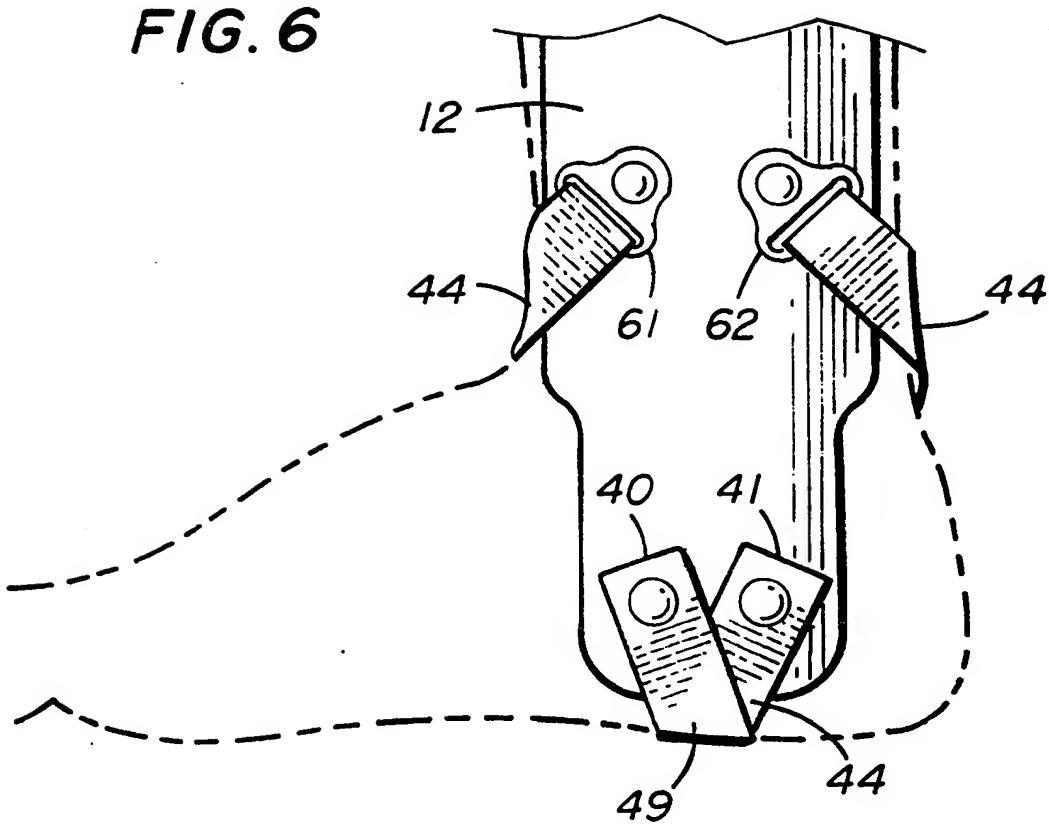
FIG. 4





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FIG. 6



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/11651

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 5/00

US CL :602/16, 23, 27, 65

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 602/6, 7, 16, 23, 27-29, 65

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 5,902,259 A (WILKERSON) 11 May 1999, Figs. 1b, 2b, 4 and 5.	1-11
X	US 5,445,603 A (WILKERSON) 29 August 1995 Figs. 4, 5 and 7.	1, 5, 8-10
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Y		2-4, 6, 7, 11
X	US 5,630,792 A (NEAL) 20 May 1997, Figs. 1, 2 and 5.	1, 8, 9
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Y		2-4



Further documents are listed in the continuation of Box C.



See patent family annex.

•	Special categories of cited documents:		
*A*	document defining the general state of the art which is not considered to be of particular relevance	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*E*	document published on or after the international filing date	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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